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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/510,378	02/22/2000	Maureen T. Cronin	18547-004131US	3064

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EXAMINER
PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
1627	13

DATE MAILED: 03/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

	Application No. <b>09/510,378</b>	Applicant(s) <b>Cronin et al</b>
	Examiner <b>Padmashri Ponnaluri</b>	Art Unit <b>1627</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Jan 8, 2002
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 52-92 is/are pending in the application.
- 4a) Of the above, claim(s) 52-81 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 82-92 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9
- 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19)  Notice of Informal Patent Application (PTO-152)
- 20)  Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The request filed on 5/8/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/510,378 is acceptable and a CPA has been established. An action on the CPA follows.
2. This application is continuation of 08/544,381; which is a continuation-in-part of 08/510,521; which is a continuation-in-part of PCT/US94/12305; which is a continuation-in-part of 08/284,064; which is a file wrapper of 08/781,550; which is a continuation-in-part of 08/143,312 which is a file wrapper of 08/441,887.
3. Claims 59-92 are currently pending in this application.
4. Applicant's election without traverse of group II, claims 82-92, filed on 1/8/02, in Paper No. 12 is acknowledged.
5. Claims 59-81 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 12.
6. Claims 82-92 are currently being examined in this application.

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7. The disclosure is objected to because of the following informalities:

Through out the specification, there are several hand written entries (copy) for sequence information. It is not clear whether applicants intend to amend the specification to enter these changes or not.

Applicants are requested to amend the specification to enter the SEQ ID NOs..

Appropriate correction is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 82-92 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. a) The length of the probe ; and b) reference sequence, is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 U. S. P. Q. 356 (CCPA 1976). The instant claims do not recite the probe length which is critical in hybridization. The probe should be long enough to allow the probe to hybridize to the reference sequence. Thus, it is essential for the invention to include the length of the probes in the array. And the specification teaches that the target sequences differ from the reference sequences at one or more positions but show high sequence identity with the reference sequence. And the references include known mutations or polymorphism associated with phenotypic changes having clinical significance. Thus, the reference sequence is known and should be closely related to the target sequence. Moreover, the

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reference sequence is a predetermined sequence such that the array of the probe sets can be prepared which are used in the instant assay. Thus, the information regarding the reference sequence is necessary.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 82-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 82-92 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the length of the probes and information regarding the reference sequence.

B) Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to determine whether the nucleotide in the target sequence is same or different from the reference nucleotide.

C) Claim 82 recites the limitation "the segment" in line 6. There is insufficient antecedent basis for this limitation in the claim.

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D) Claim 88 recites the limitation "the segment" in line 6. There is insufficient antecedent basis for this limitation in the claim.

E) claims 82 and 88 are indefinite by reciting 'segment', and it is not clear whether the probe has segments, how many segments are present in a probe, and how long each segment is .

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U. S. P. Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U. S. P. Q. 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 U. S. P. Q. 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 U. S. P. Q. 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 82-92 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,837,832. Although the conflicting claims are not identical, they are not patentably distinct from each other because the array of reference is required for practicing the instant claim methods..

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14. Claims 82-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-27 of U.S. Patent No. 6,027,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference method recites that the reference sequence is from CFTR gene, and the instant claim methods are open to any type of reference gene, which may include the CFTR gene.

15. Claims 82-92 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-30 of U.S. Patent No. 6,309,823 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant in claims do not recite what are the included in the reference sequence (open), and the biotransformation gene of reference sequence of the ‘823 patent may read on the instant claim reference sequence.

16. No claims are allowed.

17. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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Any inquiry concerning this communication should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703)308-2439. The fax number for this group is (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

P. Ponnaluri  
Patent Examiner  
Technology center 1600  
Art Unit 1627  
07 March 2002

  
**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**